REAL WORLD TESTING PLAN

GENERAL INFORMATION

Plan Report ID Number: 20211202cli

Developer Name: CliniComp, Intl.

Product Name: CliniComp | EHR

Version Number: 213.03

Certified Health IT Product List (CHPL) ID(s):15.05.05.2695.CLIN.01.00.1.200818

Developer Real World Testing Page URL: https://www.clinicomp.com/cehrt.html

Part Number: 260-00115 Rev: A Effective Date: 06 Dec 2021

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Justification For Real World Testing Approach

CliniComp has designed four real world testing measures that will address the applicable 16 real world testing criteria of which they are certified.

CliniComp is actively marketing its product's capabilities in an acute care hospital setting. Each of the 16 real world testing certification criteria will be tested in a way that produces measurable evidence of the product's ability to function successfully and demonstrate interoperability in the inpatient environment.

The entirety of the 16 real world testing certification criteria for CliniComp's certified product is not yet deployed or used by customers. Because of this, CliniComp cannot test the features that are certified to real world testing criteria in a production environment with real patient data. Instead, to demonstrate CliniComp's compliance with meeting the Real World Testing Condition and Maintenance of Certification Requirements, CliniComp will test the 16 measures on an internal server. CliniComp engages clinical consultants that are familiar with CliniComp's non-CEHRT products. These consultants will perform the Real World Tests on a bi-annual basis.

Testing will occur in June and November of 2022. Four measures encompass the certified real world testing criteria. The measures will use de-identified patient data from one of CliniComp's non-certified products for testing.

Each of the four measures will consist of measurable criteria to demonstrate successful Real World testing. The results will depict consistency of the user experience, as well as usability trending.

The testing results for 2022 will be submitted to SLI by January 15, 2023.

Standards Updates (Including Standards Version Advancement Process (SVAP) and United States Core Data for Interoperability (USCDI))

Standard (and version)	n/a
Updated certification criteria	n/a
and associated product	
Health IT Module CHPL ID	n/a
Method used for standard	n/a
update	
Date of ONC ACB notification	n/a
Date of customer notification	n/a
(SVAP only)	
Conformance measure	n/a
USCDI updated certification	n/a
criteria (and USCDI version)	

Measure/Workflow Used in Overall Approach

Measure/Workflow	Description	
CQM	User electronically creates a data file for transmission of clinical quality measurement data of all patients admitted during the testing period.	
	 a) Report percentage of successful file creation for all patients in the denominator of each Clinicomp certified CQM. §170.315(c)(3) 	
	Report percentage of a user successfully exporting a single data file of a patient (admitted during the testing period) that meets criteria to be included in the denominator of each certified CQM. § 170.315(c)(1)	
	Report percentage of a user successfully importing a single file for each certified CQM. §170.315 (c)(2)	
Care Coordinator	User selects 10 patients from the appropriate testing pool and reports percentage of successfully accomplishing the following tasks:	
	a. Send a SOC document. §170.315 (b)(1)	
	b. Viewing a received SOC document. §170.315 (b)(1)	
	c. Viewing the reconciled list (1 allergy, 1 medication, 1	

The Office of the National Coordinator for Health Information Technology

Measure/Workflow	Description	
	problem). §170.315 (b)(2)	
	 d. Creating an export summary on one patient, tagged as private, in real time. §170.315 (b)(6)(7) 	
	e. Creating an export summary on one patient for last 2 months. §170.315 (b)(6)	
	f. Viewing a received SOC document, tagged as secure. §170.315 (b)(8)	
	 For the same 10 test patients, user documents success rate of accomplishing the following Care Plan activities: §170.315 (b)(9) 	
	a. accessed and created; recorded; changed.b. Received.	
	 For the same 10 test patients, user documents success rate of creating an immunization record for submission to a registry. §170.315 (f)(1) 	
	 For the same 10 test patients, user documents success rate of requesting and viewing imported immunization history and forecast from a registry. §170.315 (f)(1) 	
	For the same 10 test patients, user documents success rate of creating a syndromic-based public health surveillance document for transmittal to a public health agency. §170.315 (f)(2)	
	For the same 10 test patients, user documents success rate of sending patient's health information to a recipient via direct address. §170.315 (h)(1)	
Patient	User enacts the patient role from the appropriate testing pool of patients and documents success rate of viewing and sending the downloaded inpatient summary via the Patient Portal to a third party. The user will do this for 10 patients. §170.315 (e)(1)	
API	User selects 10 patients from the appropriate testing pool and documents success rate of using a third party application to access specific patient data for the desired patient for a given time frame. §170.315 (g)(7-9)	

Associated Certification Criteria

Measurement/Metric	Associated Certification Criteria	
CQM	(c)(1-3)	
Care Coordinator	(b)(1-2); (b)(6-9); (f)(1-2); (h)(1)	
Patient	(e)(1)	
API (g)(7-9)		

Justification for Selected Measurement/Metric

Measurement/Metric	Justification	
CQM	To demonstrate successful Real World Testing, the results for each CQM criterion are measured as a percentage of successful transmission. The data can easily be compared on a bi-annual basis to ensure interoperability and verify the consistency of the user experience. It will also provide visibility on usability trending.	
Care Coordinator	To demonstrate successful Real World Testing, the results of the Care Coordinator criterion are measured as a percentage of success. The results will be viewed as trending data for the two testing periods in the year.	
Patient	To demonstrate successful Real World Testing, the results of the Patient criterion are measured as a percentage of successful transmission. The results will be viewed as trending data for the two testing periods in the year.	
API	To demonstrate successful Real World Testing, the results of the API criterion are measured as a percentage of successful access. The results will be viewed as trending data for the two testing periods in the year.	

Care Setting(s)

Measurement/Metric	Care Setting	Justification
CQM	Inpatient Acute	Clinicomp is certified to several inpatient CQMs. Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
Care Coordinator	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
Patient	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.
API	Inpatient Acute	Clinicomp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real World Testing criteria.

Expected Outcomes

Measurement/Metric	Expected Outcomes	
CQM	The expected percentage of success for each criterion is 85%. Over the	
	year, the expectation is that the rate of success will not decrease.	
Care Coordinator	The expected percentage of success for each criterion is greater than 85%	
	and to remain consistent with each testing phase. The usability of the	
	tester is expected to be positive. Clinicomp also expects suggestions for	
	ways to improve the user's experience.	
Patient	The expected percentage of success for each criterion is greater than 85%	
	and to remain consistent with each testing phase. Clinicomp will consider	
	all suggestions made to improve workflow and the user experience.	
API	The expected percentage of success for each criterion is greater than 85%	
	and to remain consistent with each testing phase. Clinicomp will consider	
	all suggestions made to improve workflow and the user experience.	

Schedule Of Key Milestones

Key Milestone	Care Setting	Date/Timeframe
Collect patient data	Inpatient Acute	1/1/22 – 5/31/22
Test de-identified patient data	Inpatient Acute	6/1/22 – 6/30/22
Collect patient data	Inpatient Acute	6/1/22 – 10/31/22
Test de-identified patient data	Inpatient Acute	11/1/22 – 11/30/22
Report Real World Test Results to SLI	Inpatient Acute	01/15/23

Attestation

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Authorized Representative Signature:

Date: 12/01/2021

ⁱ Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets; certified health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and EHI is received by and used in the certified health IT. (85 FR 25766)

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2022 Real World Testing Results

ONC HealthIT Certification Program



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Product Name: CliniComp|EHR

Version Number: 213.03

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15.05.05.2695.CLIN.01.00.1.200818 (previous)

Developer RWT Plan Page URL: https://www.clinicomp.com/cehrt.html
Developer RWT Results Page URL: https://www.clinicomp.com/cehrt.html

CHANGES TO ORIGINAL PLAN

In 2020, CliniComp, Intl. software was certified using the ONC data and testing tools. Using the tools is not permitted for RWT plans, therefore some tests could not be completed because the software is not deployed at a customer site.

Real world testing is intended to verify and publicly share that deployed certified software is interoperable and data is exchanged. CliniComp did not have any component of their certified software deployed at a customer site in 2022.

Our plan is to test with real patient data on a production server when we have a customer using any or all our certified software. We did not obtain a customer in 2022. We are actively marketing our services to acute inpatient hospitals and plan to have a customer in 2023 or 2024. Until then, we are limited to using Use Cases and testing on an internal, certified software server.

Summary of Change: The intent and process of Real-World Testing involves vendors using deployed software to test production data, actions, and publicly sharing results to demonstrate compliance. Considering this intent, and the fact that CliniComp's certified software was not in production at customer sites in 2022, it was determined that CliniComp could best comply with this condition of certification by testing each measure with a User Story on an internal server with the certified software. The 2022 Real World Test Plan was inclusive of 15 measures; however, §170.315 (g)(8) was removed from CCI's ONC certification program in 2022. §170.315 (g)(8) is not included in this Real World Test Results Report.

Reason: The collection of patient data from production servers and testing each measure biannually was removed from the test plan due to a lack of technical feasibility. The complexity of the test plan did not add value or further quantify compliance with the measures since the software is not in production.

Challenges: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. Many of the measures can only be partially replicated without having the certified software on a production server.



SUMMARY OF TESTING METHODS

Within the first year, 2022, of RWT results collection and monitoring, CliniComp did not have their certified software in production. Although the intent of Real-World Testing as a condition of certification was in relation to deployed software, CliniComp is demonstrating interoperability and data exchange on internal servers with certified software and user stories.

In 2020, CliniComp, Intl. software was certified using the ONC data and testing tools. Using the tools is not permitted for RWT plans, therefore some tests could not be completed because the software is not deployed at a customer site.

The measures listed in the <u>Metrics and Outcomes</u> section cover all 14 certified criterion and summarize their original test method, the specific change in test plan and reason, interoperability results, and any associated risks.

METRICS AND OUTCOMES

In this section, we describe how the data collected in our Real-World Testing is compliant with certification criteria and exchanging EHI in an acute setting. We are not able to demonstrate that EHI is received and used in the certified health IT because the certified software is not deployed. See the Expected Outcomes and Challenges sections of the 14-criterion listed here.

CQM — Record and Export: §170.315(c)(1)

Test Method: Report percentage of a user successfully exporting a single data of a patient for all certified CQMs.

Summary of Test Plan Change: On internal server, chart documentation supporting fields of the CMS9v11 CQM was performed. User generated a QRDA file for patient in denominator of CMS9v11 CQM.

Reason: Because the software is not deployed, replicating this User Story for all 8 CQMs was duplicative and did not add value to the intent of the ONC condition of certification.

Expected Outcomes: User can document on CQM measures in CliniComp | EHR and generate a QRDA file for submission to CMS.

Results Demonstrating RW Interoperability: QRDA file successfully generated to support data exchange/interoperability and ensure the reports can be electronically submitted to CMS.

Success rate: Document on CQM & Generate Export File in QRDA Format: 1/1 = 100% **Risk:** When the software is deployed, minor defect corrections may be requested by the customer. Successfully generating a QRDA file renders the risk low.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging.



CQM — Import and Calculate: §170.315(c)(2)

Test Method: Report percentage of a user successfully importing a single file for each certified CQM.

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: Successfully demonstrating importing a single file for each certified CQM was done in 2020 using the ONC test data and testing tools. It is not feasible to perform this test on customer data until the software is deployed.

Expected Outcomes: The QRDA submission file generated by CliniComp|EHR and uploaded to CMS is an exact match in measure calculations with CMS.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure could not be tested without having the certified software on a production server.

CQM – Report: §170.315(c)(3)

Test Method: User creates a data file for all patients in the denominator for all certified CQMs. Report percentage of successful file creation for all patients in the denominator of each CliniComp certified CQM.

Summary of Test Plan Change: On internal server, generated a file with patients in denominator for CMS9v11.

Reason: Demonstrating compliance with 1 CQM, rather than all. There is no value added to duplicate proven compliance with every certified clinical quality measures.

Expected Outcomes: User successfully creates a data file for appropriate patient group. **Results Demonstrating RW Interoperability:** QRDA file successfully generated to support data exchange/interoperability and ensure the reports can be electronically submitted to CMS.

Success rate: QRDA file generated with multiple pts from denominator of single measure: 1/1 = 100%

Risk: When the software is deployed, minor defect corrections may be requested by the customer. The risk is minimal with the successful generation of a QRDA file.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging.



Care Coordinator – Transitions of Care: §170.315 (b)(1)

Test Method: For ten test patients: Send a SOC document; View a received SOC document. **Summary of Test Plan Change:** User story for one patient, to demonstrate user can create a SOC and take action to send the document. Testing the criteria of viewing a received SOC was removed.

Reason: Receiving/viewing a SOC document was demonstrated successfully using the test tool but is not feasible using customer data until the software is deployed at a customer site. **Expected Outcomes:** RW/T will demonstrate interoperability through CliniComplEHR's

Expected Outcomes: RWT will demonstrate interoperability through CliniComp | EHR's conformance to §170.315 (b)(1). SOC documents can be viewed, sent, and received.

Results Demonstrating RW Interoperability: User can create an SOC and there are actions available to send the SOC – the steps for receiving and viewing are not actionable until the software is deployed. Additionally, the test tools were not to be used in RWT certification.

Success Rate:

- creating and take action to send SOC: 1/1 = 100%
- viewing a received SOC: Criterion Removed

Risk: A customer may request defect corrections when the software is deployed but the risk is minimal with the successful demonstration of receiving and viewing a SOC document using the test tool.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. One component of this measure could not be testing without having the certified software on a production server.

Care Coordinator — Clinical Info Rec & Incorp: §170.315 (b)(2)

Test Method: For ten test patients: Viewing the reconciled list (1 allergy, 1 medication, 1 problem) and incorporating CDA data.

Summary of Test Plan Change: User story for one patient, rather than ten, to demonstrate user can view a reconciled list of allergies, medications, and problems. Testing the criteria of incorporating CDA removed.

Reason: There is no value added to duplicate user stories for the same measure. One User Story sufficiently demonstrates compliance. Incorporating CCD into clinical reconciliation was demonstrated successfully using the test tool but is not feasible using customer data until the software is deployed at a customer site.

Expected Outcomes: CliniComp|EHR allows users to incorporate CDA and reconcile clinical information.



Results Demonstrating RW Interoperability: User can view pre-post reconciliation of meds, allergies, and problems.

Success Rate:

- viewing a reconciled list of meds, allergies, & problems: 1/1 = 100%
- incorporating CDA data: Criterion Removed

Risk: None

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. One component of this measure could not be testing without having the certified software on a production server.

Care Coordinator — Data Export: §170.315 (b)(6) & Security Tags: §170.315 (b)(7)

Test Method: Creating an export summary for ten patients, tagged as private, in real-time. **Summary of Test Plan Change:** User Story to create an export summary for one private patient.

Reason: Duplicating user stories for the same measure would be redundant. One User Story sufficiently demonstrates compliance.

Expected Outcomes: CliniComp | EHR allowed user to create an SOC file for the selected patient.

Results Demonstrating RW Interoperability: Export summary successfully created.

Success Rate: Export Summary: 1/1 = 100%

Risk: Receiver of exported summary may not be able to read the summary. The risk is low since we successfully demonstrated the summary was readable by the receiver when we validated the test using the test tool.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging.

Care Coordinator — Security Tags — SOC — Receive: §170.315 (b)(8)

Test Method: Viewing a received SOC document, tagged as secure.

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. The software is not deployed and therefore this test can only be done using the testing tools.

Expected Outcomes: User can receive and view a SOC **Results Demonstrating RW Interoperability:** none



Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested. The risk is low with the successful demonstration of viewing a received SOC document using the ONC test data and testing tools.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Care Coordinator — Care Plan: §170.315 (b)(9)

Test Method: User documents success rate of accomplishing Care Plan activities (accessed & created, recorded, changed, and received) for ten patients.

Summary of Test Plan Change: User Story to demonstrate accessing, creating, recording, and changing care plans for 1 patient. Testing the receipt of a care plan was removed from the test plan due to a lack of technical feasibility.

Reason: One User Story sufficiently demonstrates compliance. Duplicating user stories will have the same result. Receiving a care plan was successfully demonstrated in 2020 using the testing tools. Since the software is not deployed, it is not feasible to demonstrate receipt of a care plan without using the tools.

Expected Outcomes: User demonstrates, via CliniComp|EHR, interoperability and EHI received and used in deployed certified software.

Results Demonstrating RW Interoperability: Creation and manipulation of Care Plans was demonstrated. Receiving a care plan is not a technically feasible without using testing tools since there is not a production server with the certified software.

Success Rate:

- Compliant with criterion to create and manipulate Care Plan: 1/1 = 100%
- Interoperability receiving EHI: Criterion Removed

Risks: Receiving Care Plan documents may not be able ingestible by CliniComp. The risk is low since we demonstrated successfully received and viewed a care plan document using the ONC data and testing tools.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. Many of the measures can only be partially replicated without having the certified software on a production server.



Care Coordinator – Transmission to Immunization Registries: §170.315 (f)(1)

Test Method: For ten test patients, user documents success rate of creating and submitting an immunization record to a registry; requesting and viewing imported immunization history and forecast from a registry.

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools.

The steps for transmitting, importing, and viewing an immunization record to/from a registry are not actionable until the software is deployed or using the ONC test data and test tools.

Expected Outcomes:

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested. The risk is low since the test was successfully performed in 2020 using ONC test data and testing tools.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measures cannot be replicated without having the certified software on a production server.

Care Coordinator – Transmission to Public Health Agencies: §170.315 (f)(2)

Test Method: User documents success rate of creating a syndromic-based public health surveillance document for transmittal to a public health agency for ten patients.

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. Performing this test requires deployed software or utilizing ONC test data and testing tools.

Expected Outcomes: CliniComp|EHR accommodates creating and sending syndromic surveillance data to the appropriate registry.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.



Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Care Coordinator – Direct Project: §170.315 (h)(1)

Test Method: For ten patients, user documents success rate of sending patient's health information to a recipient via direct address.

Relied Upon Software: EMR Direct Data Exchange Protocol API (Version 1.3.2)

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. The software is not deployed and therefore this test can only be done using the testing tools. The technical requirements are not feasible without a production server.

Expected Outcomes: Ability to electronically send and receive EHI to a third party.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

Patient - VDT: §170.315 (e)(1)

Test Plan: User enacts the patient role, for ten patients, from the appropriate testing pool of patients and documents success rate of viewing and sending the downloaded inpatient summary via the Patient Portal to a third party.

Summary of Test Plan Change: User story – view and email SOC from patient portal.

Reason: Duplicating user stories for the same measure would be redundant. One User Story sufficiently demonstrates compliance.

Expected Outcomes: User can perform VDT without assistance from the patient portal.

Results Demonstrating RW Interoperability: SOC sent successfully.

Success Rate: SOC VDT: 1/1 = 100%

Risk: none

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging.



API – Application Access: Patient Selection & Data Request: §170.315 (g)(7)(9)

Test Plan: User selects 10 patients from the appropriate testing pool and documents success rate of using a third-party application to access specific patient data for the desired patient for a given time frame.

Summary of Test Plan Change: Testing the criteria was removed from the test plan due to a lack of technical feasibility.

Reason: The test plan was successfully demonstrated in 2020 using the ONC test data and testing tools. The software is not deployed and therefore this test can only be done using the testing tools. The technical requirements are not feasible without a production server.

Expected Outcomes: An API is used to access patient data.

Results Demonstrating RW Interoperability: none

Success Rate: Criterion Removed

Risk: When a customer uses this certified software, there might be some minor defect corrections requested.

Challenges Encountered: Conducting real world testing on production servers with certified software that is not deployed in production is challenging. This measure cannot be replicated without having the certified software on a production server.

STANDARDS UPDATES

	Yes, I have products certified with voluntary SVAP or USCDI standards.
х	No, none of my products include these voluntary standards.

CARE SETTING

• Inpatient Acute: CliniComp is actively marketing its inpatient product. Inpatient acute is the appropriate care setting to demonstrate compliance and adherence to the Real-World Testing criteria.



KEY MILESTONES

Key Milestone	Care Setting	Date/Timeframe
Revised Test Plan	Inpatient Acute	Q1, 2022
Gathered Data	Inpatient Acute	Q2-4, 2022
Analyze Data	Inpatient Acute	Q4 – 1.26.23
Create Report	Inpatient Acute	1.26.23 – 2.3.23